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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,943	05/24/2001	Robert I. Lehrer	8067-111-999	7913

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,943

Applicant(s)

Lehrer et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Part III DETAILED ACTION

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 16-30 (in part related to linear compounds), 15, drawn to linear peptides and their pharmaceutical compositions, classified in classes 514, subclass 13.
- II. Claims 1, 16-30 (in part related to bicyclic compounds), 2-8 drawn to bicyclic peptides and their pharmaceutical compositions, classified in class 514, subclass 10.
- III. Claims 1, 16-30 (in part related to monocyclic compounds), 9-14, drawn to monocyclic peptides and their pharmaceutical compositions, classified in class 514, subclass 11.
- IVa-c. Claims 31-37 drawn to methods to inhibit the growth of microbe or virus.
- Va-c Claim 38 drawn to method of inactivating endotoxin.
- VI a-c Claims 39-47 drawn to method of treat a microbial or viral infection.

Subgroups a-c in Groups IV-VI are designated to method of use utilizing compounds of

different structure, as follows:

- a. Methods of use of linear peptides, classified in class 514, subclass 13.
- b. Methods of use of monocyclic peptides, classified in class 514, subclass 11.
- c. Methods of use of bicyclic peptides, classified in class 514, subclass 10.

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The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are patentably distinct from each other because of the materially different structures of the compounds they are claiming. The inventions are drawn to independent and/or patentably distinct peptides since each would be expected (and do) to possess distinctly different structure (e.g., secondary and tertiary structure), and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Further, a linear peptide sequence would not anticipate or suggest particularly cyclized peptide structure, especially, as in the instant case, when several possibilities for cyclization exist.

Inventions I-III and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods IV-VI are alternate methods of using the compounds of Groups I-III. Further, the methods of use of Groups IV-VI can be practiced alternatively with the products of Group I or Group II or Group III (as specified by further subdivision of the groups into subgroups a-c).

Groups IV, V are drawn to patentably distinct methods which are not connected in design, operation or effect. The methods are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. In the instant case, a method of inhibition of growth of

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microbes or viruses (Group III) have different effects than the method of inactivating endotoxin. In addition, each method has separate patentability and enablement requirements. In addition, each method has separate patentability and enablement requirements. In addition, each method has separate patentability and enablement requirements. In addition, each method has separate patentability and enablement requirements.

Groups IV, V and Group V are drawn to patentably distinct methods, as they are drawn to *in vitro* and *in vivo* methods respectively, and have different modes of operation. In addition, each method has separate patentability and enablement requirements.

Inventions of subgroups a-c of Groups III-V are drawn to methods of use of materially different products, as exemplified by their different classification.

Because these inventions are distinct for the reasons given above,

- have acquired a separate status in the art as shown by their different classification;
 - the patent and/or sequence or structure search required for different groups is different, and/or their necessity for non-coextensive literature searches; and/or
 - the compounds (and methods of use thereof) have acquired a separate status in the art because of their recognized divergent subject matter,
- restriction for examination purposes as indicated is proper.

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP 821.04)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Species Requirement

After the election of one of the Groups I-VI a related Election of species requirement is applicable.

Claims of the Groups are generic to a plurality of disclosed patentably distinct species comprising cysteine, penicillamine, basic, hydrophobic, polar/large, small amino acid residues, as defined for A1-A3, C3-C6, A7, C8, A9-A12, C13, A14, C15-C17, A18. The claims of Groups are generic to a plurality of disclose patentably distinct species of peptides, which encompass a plethora

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of different compound species that require a burdensome classification, and/or bibliographic, manual and computer search. Accordingly, regardless of which group is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., a single compound), even though the requirement is traversed.

In addition, if a method of use group is elected, election of species is required for:

- i) one of disclosed species of bacteria from those listed in, e.g., claim 33, and
- ii) one of disclosed species of microbes or viruses from those listed in, e.g., claim 34

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the particular condition to be treated, even though this requirement is traversed.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang can be reached on (703) 308-0254. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

April 30, 2003

mlb

